TFW 1648

Dkt. 57906-B/JPW/JRM

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	William C. Olson & Paul J. Maddon	
Serial No.	:	09/594,983	Examiner: Peng, Bo
Filed	:	June 15, 2000	Group Art Unit: 1648
For	:	CCR5 ANTIBODY PA14	
Notice of Allowance mailed	:	December 19, 2006	
Confirmation No.	:	8686	

1185 Avenue of the Americas
New York, New York 10036
February 12, 2007

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

COMMUNICATION CONFIRMING JANUARY 9, 2007 TELEPHONE CONFERENCE WITH EXAMINER PENG AND FORWARDING COPY OF PREVIOUSLY SUBMITTED NEW FIGURE 4

This Communication is submitted after the mailing of a Notice of Allowance but before payment of the issue fee in connection with the above-identified application. The issue fee is due March 19, 2007 and has not yet been paid. Accordingly, this Communication is being timely filed.

This Communication is submitted to confirm the January 9, 2007 telephone conference between Examiner Peng of the United States Patent and Trademark Office and James Major of the undersigned's office and to forward to the Examiner a copy of new Figure 4 previously submitted to the U.S. Patent Office on September 13, 2002 in connection with the subject application.

The United States Patent and Trademark Office issued an Office Action in connection with the subject application on March 13, 2002, a copy of which is attached hereto as **Exhibit 1**. The March 13, 2002 Office Action indicated that Figure 4 was objected to because the numbers in the boxes were allegedly very hard to read. The March 13, 2002 Office Action further indicated that corrected drawings were required in reply to the March 13, 2002 Office Action.

In response, Applicants on September 13, 2002 filed an Amendment In Response to March 13, 2002 Office Action And Petition For A Three Month Extension of Time, including as Exhibit B a new Figure 4. A copy of this previously filed new Figure 4 is attached hereto as **Exhibit 2**.

On January 9, 2007, Mr. Major telephoned Examiner Peng to enquire whether the drawings filed June 15, 2000 and new Figure 4 submitted September 13, 2002 had been accepted. Examiner Peng advised Mr. Major that new Figure 4 was not present in the Image File Wrapper of the subject application.

As evidence of receipt by the United States Patent and Trademark Office of new Figure 4, applicants attach hereto as **Exhibit 3** a copy of the postcard receipt stamped by the U.S. Patent Office.

According to M.P.E.P. §503, "[a] postcard receipt which itemizes and properly identifies the items which are being filed serves as *prima facie* evidence of receipt in the USPTO of all the items listed thereon on the date stamped thereon by the USPTO." M.P.E.P. §503 also indicates that upon receipt of the papers, "[i]f any of the items listed on the postcard are not being submitted to the USPTO, those items will be crossed off and the postcard initialed by the person receiving the items."

Applicants note that the stamped returned postcard indicates the receipt date of September 18, 2002 for, *inter alia*, new Figure 4 listed on the postcard. Applicants also note that the postcard has **not** been annotated to indicate that new Figure 4 listed on the postcard was not received by the United States Patent and Trademark Office. Accordingly, applicants maintain that the attached postcard is *prima facie* evidence of receipt at the United States Patent and Trademark Office of new Figure 4 listed thereon.

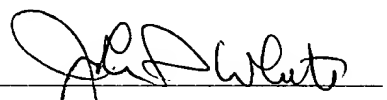
Accordingly, applicants maintain that applicants timely submitted new Figure 4 to the United States Patent and Trademark Office and the United States Patent and Trademark Office received new Figure 4. However, for the convenience of the Examiner, applicants have attached hereto as **Exhibit 2** a copy of new Figure 4.

The Examiner is respectfully requested to approve new Figure 4 and to enter it into the file of the subject application.

If a telephone interview would assist in advancing consideration of this Communication, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Communication. However, if any fee is required authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



John P. White
Registration No. 28,678
Attorney for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
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(212) 278-0400

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

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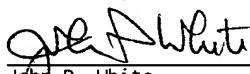
Alexandria, VA 22313-1450



2/12/07

John P. White — Date
Reg. No. 28,678

57906-B JPW

Office Action Summary

Application No.	Applicant(s)	
09/594,983	WILLIAM C. OLSEN ET AL.	
Examiner	**Art Unit**	
Shanon A. Foley	1648	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *78-99* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *78-98* is/are rejected.

7)☒ Claim(s) *98 and 99* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

3/13/2002
3 Mos: 6/13/2002
4 Mos: 7/13/2002
5 Mos: 8/13/2002
6 Mos: 9/13/2002
SMC

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 June 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 & 12
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Sequence Error Report & Notice to Comply*

Applicants : William C. Olson & Paul J. Maddon
U.S. Serial No. : 09/594,983
Filed : June 15, 2000

Exhibit 1

DETAILED ACTION

The Examiner of your application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648, Examiner Foley.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Election/Restrictions

Applicant's election of group V and species PA14 with traverse is acknowledged. Restriction between the humanized and non-humanized monoclonal antibody forms is withdrawn. Therefore, all pending claims 78-99 are under consideration. Should the elected species PA14 be free of prior art, a subsequent search for the other species will ensue.

Specification

The abstract of the disclosure is objected to because it must be 150 words or less. Correction is required. See MPEP § 602 (j).

Drawings

The drawing of Figure 4 is objected to because the numbers in the boxes are very hard to read. A proposed drawing correction or corrected drawings are required in reply to the Office

action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 88, 89, and 98 are objected to because of the following informalities: "P11" is presumably "PA11". Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 78-88 and 90-98 are provisionally rejected under the judicially created doctrine of double patenting over claims 78 and 79, 80, respectively, of copending Application No. 09/464,9052. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: monoclonal antibody PA14 and any other antibody that binds to the same epitope as PA14.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 93 and 95-97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 93 is vague and indefinite because the metes and bounds of what is intended or encompassed by "some, most, or all of the amino acids" in lines 1-2 and 4-5 cannot be determined.

Claims 95 and 96 state that donor immunoglobulin comprises "the CDRs". Which CDRs are being referred to?

Claims 96 and 97 are confusing because claim 96 states that the framework of a donor immunoglobulin is derived from a human immunoglobulin, while the donor immunoglobulin is murine in claim 97. Is the framework of the antibody derived from human, except for the murine amino acids immediately adjacent to the CDRs? Or, can there be two possible donors for each humanized antibody, i.e., one from human and another from murine?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 88, 89 and 98 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that hybridomas to make monoclonal antibodies PA8-PA12 and PA14 are required to practice the claimed invention because they are necessary limitations for the success of the invention as stated in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the hybridomas that make monoclonal antibodies PA8-PA12 and PA14. See 37 CFR 1.802.

The specification does not provide a repeatable method for obtaining the hybridomas that make monoclonal antibodies PA8-PA12 and PA14 and it is not apparent if it is readily to the public. Applicant's deposit statement on specification pages 13-14 does not indicate the extent of public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 78-88, 90, 91, 93, 94, and 97 are rejected under 35 U.S.C. 102(a) as being anticipated by Wu et al. (WO 98/18826).

The claims are drawn to a monoclonal antibody that binds to the N-terminus and/or one of three extracellular loops of CCR5 and is humanized by incorporation of a human immunoglobulin framework.

Wu et al. teaches that monoclonal antibodies 5C7 and 3A9 are both specific for the N-terminus of the CCR5 receptor and monoclonal antibody 2D7, which was generated from murine IgG1, has epitope specificity for the second extracellular loop of the CCR5 receptor, see page 15, lines 18-21 and page 72, line 31, and claims 1-3, 27-29, 55, and 56. Wu et al. also teaches a bispecific antibody that binds to the N-terminus and the second extracellular loop of CCR5, see page 15, line 27 to page 16, line 5, and humanized forms of the antibodies, where the framework and the consensus are derived from a human immunoglobulin or multiple immunoglobulin molecules, where the regions surrounding the CDR regions have been replaced by human immunoglobulin molecules, see page 19, line 31 to page 21, line 32. Claims 80 and 82-87 are drawn to the epitope comprising specific amino acid sequences. Although Wu et al. do not specifically teach the amino acid sequences within the epitopes at the N–terminus and the second

extracellular loop, it is known in the art that the specific amino acids in claims 80, 82-87 exist in these CCR5 regions, evidenced by Chen et al. (Journal of Virology. 1997; 71 (4): 2705-2714, see especially page 2708). Therefore, the monoclonal antibodies 5C7, 3A9, and 2D7 of Wu et al. bind to CCR5 epitopes that inherently possess the claimed amino acids.

Claims 78-83 and 88 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Wu et al. (J. Exper. Med. Oct. 1997; 186 (8): 1373-1381).

The claims are drawn to a monoclonal antibody that binds to the N-terminus or one of the three extracellular loops of CCR5.

Wu et al. teaches a monoclonal antibody, murine IgG1 2D7, which binds to the second extracellular loop of CCR5 and another monoclonal antibody, 3A9, which binds to the N-terminal region of CCR5, see the second paragraph of the second column on page 1374 and the paragraph bridging the columns on page 1375. Although Wu et al. do not specifically teach the amino acid sequences within the epitopes at the N–terminus and the second extracellular loop, it is known in the art that the specific amino acids in claims 80, 82-83 exist in these CCR5 regions, evidenced by Chen et al. (Journal of Virology. 1997; 71 (4): 2705-2714, see especially page 2708). Therefore, the monoclonal antibodies 3A9 and 2D7 of Wu et al. bind to CCR5 epitopes that inherently possess the claimed amino acids.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 84-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (J. Exper. Med. Oct. 1997; 186 (8): 1373-1381) and in further view of Hill et al. (Virology. Sept. 1998; 248: 357-371).

The claims are drawn to a monoclonal antibody to CCR5 that binds to an epitope at the N-terminus and the second extracellular loop of CCR5.

See the teachings of Wu et al. above. Wu et al. does not teach a monoclonal antibody with specificity to an epitope on both the N-terminus and the second extracellular loop of CCR5, but does teach monoclonal antibodies that separately bind to each of these regions.

One of ordinary skill in the art at the time the invention was made would have been motivated to make a bispecific antibody that binds to the N-terminus and the second extracellular loop of CCR5 to effectively inhibit HIV virus entry and inhibit any HIV virus that binds to either or both epitopes. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation in producing the claimed invention because Hill et al. teaches that the N-terminus of CCR5 plays an essential role in the entry of diverse HIV envelope proteins. Wu et al. teaches that the second extracellular loop of CCR5 is an ideal target site for HIV inhibitors and that efficient inhibition of HIV is achieved by monoclonal antibody recognition of either the second extracellular loop or the N-terminus of CCR5. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Claims 90-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (J. Exper. Med. Oct. 1997; 186 (8): 1373-1381).

The claims are drawn to a humanized form of the instant monoclonal antibody that binds to the N-terminus or the second extracellular loop of CCR5 and product-by-process construction of the humanized antibody.

See the teachings of Wu et al. above. Wu et al. does not teach a humanized form of the monoclonal antibody 2D7 or 3A9.

However, one of ordinary skill in the art at the time the invention was made would have been motivated to humanize the monoclonal antibody of Wu et al. to characterize host immune response and antibody efficiency and effectiveness for use in *in vivo* assays. A humanized form of the monoclonal antibody of Wu et al. would have the added advantage eliciting a diminished immune response against the recombinant antibody, while retaining the desired functional capacity of reacting with the specific epitope. Further, one of ordinary skill in the art would have been motivated to use the human immunoglobulin framework to maintain the conformation of the CDR region from the no-humanized form. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation in producing a humanized antibody of Wu et al. because conventional techniques for humanizing antibodies are known in the art. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 92, 95, and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. WO 98/18826 or in the alternative, Wu et al. (J. Exper. Med. Oct. 1997; 186 (8): 1373-1381).

The claims are drawn to the monoclonal antibody containing a framework from a human immunoglobulin IgG1, IgG2, IgG3, IgG4, IgA, or IgM.

See the teachings of Wu et al. above (both references). Neither reference teaches the framework of the monoclonal antibodies to be IgG1, IgG2, IgG3, IgG4, IgA, or IgM. However, it would have been obvious for one of ordinary skill in the art at the time the invention was made to obtain the antibody framework from any of the human immunoglobulins to maintain the conformation of the CDR region and to render the recombinant antibodies less immunogenic once administered. Further, one of ordinary skill in the art would have been motivated to maintain the donor amino acid sequences immediately adjacent to the CDR domains to assure that when the framework portion of the antibody is added, the CDR domain remains intact. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for producing the claimed invention because humanizing antibodies using human IgG is conventional technique for humanizing recombinant antibodies. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Allowable Subject Matter

Claims 98 and 99 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and satisfaction of all deposit and availability requirements under the Budapest Treaty.

Claims 98 and 99 are drawn to allowable subject matter because the prior art does not teach or suggest the instant monoclonal antibodies or the hybridomas producing the antibodies. These claims would be allowable if claim 98 were drafted in independent form

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley/SAF
February 27, 2002

James C. Housel 3/11/02

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Notice of References Cited

Application/Control No.	Applicant(s)/Patent Under Reexamination	
09/594,983	WILLIAM C. OLSEN ET AL.	
Examiner	Art Unit	Page 1 of 1
Shanon A. Foley	1648	

U.S. PATENT DOCUMENTS

		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N	WO 98/18826	05-1998	PCT	Wu et al.	
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Wu et al. J. Exper. Med. Oct. 1997; 186 (8): 1373-1381.
	V	Chen et al. (Journal of Virology. 1997; 71 (4): 2705-2714.
	W	Hill et al. (Virology. Sept. 1998; 248: 357-371).
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Application No.: 09/594983

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☒ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other: _____

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:
For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
PatentIn Software Program Support (SIRA)
Technical Assistance.....703-287-0200
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TELECOPY/FACSIMILE TRANSMISSION

DATE: 4/15/02
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FROM: SHANON FOLEY
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FAX NUMBER: (703) 308-4426
PHONE NUMBER: (703) 308-3983

TO: John P. White; Attn: MARK FARLEY
FIRM: Cooper + Dunham
ATTORNEY'S DOCKET # OR SERIAL: 57906-B/JPW/SHS
FAX/TELECOPIER NUMBER: (212) 391-0525

COMMENTS: Raw sequence error listing for 09/594983.

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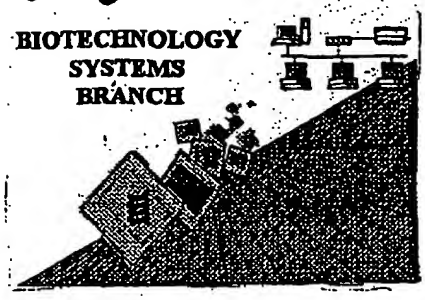

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Application Serial Number: 09/594,983
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PATENTIN 2.1 e-mail help: patin21help@uspto.gov or phone 703-306-4119 (R. Wax)
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DATE: 01/22/2002
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--> 3 <130> FILE REFERENCE: 57906-B<140> PCT/99US/30345<141>
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--> 4 <141> CURRENT FILING DATE: 2000-06-15
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449

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INFORMATION DISCLOSURE CITATION
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Atty. Docket No.	Serial No.
57906-PW/SHS/GJC	09/594,983
Applicants: William C. Olson, et al.	
Filing Date: June 15, 2000	Group

U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

GAA	AC	Doranz, B.J., J. Rucker, Y. Yi, R. Smyth, M. Samson, S.C. Peiper, M. Parmentier, R.G. Collman, and R.W. Doms. A Dual-Tropic Primary HIV-1 Isolate That Uses Fusin and Beta-Chemokine Receptors CKR-5, CKR-3, and CKR-2b as Fusion Cofactors. Cell 85: 1149-1158;
	AD	Deng, H., R. Liu, W. Ellmeier, S. Choe, D. Unutmaz, M. Burkhart, P.D. Marzio, S.Marmon, R.E. Sutton, C.M. Hill, C.B. Davis, S.C. Peiper, T.J. Schall, D.R. Littman, and N.R. Landau, Identification of a Major Co-Receptor for Primary Isolates of HIV-1. Nature 381: 661-666;
GAA	AE	Feng, Y., C.C. Broder, P.E. Kennedy, E.A. Berger. HIV-1 Entry Cofactor: Functional cDNA Cloning of a Seven-Transmembrane, G Protein-Coupled Receptor. Science 272: 872-877;

EXAMINER	DATE CONSIDERED
Shaun A. Hutt	2/27/02

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57[illegible]B/JPW/SHS/GJC	09/594,985
Applicants: William C. Olson, et al.	
Filing Date: June 15, 2000	Group

U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation Yes	Translation No

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	W	Vijh-Warrier, S., A. Pinter, W.J. Honnen and S.A. Tilley. 1996. Synergistic neutralization of human immunodeficiency virus type 1 by a chimpanzee monoclonal antibody against the V2 domain of gp120 in combination with monoclonal antibodies against the V3 loop and the CD4-binding site. J. Virol. 70:4466-4473;
	X	Wu, L., G. LaRosa, N. Kassam, C.J. Gordon, H. Heath, N. Ruffing, H. Chen, J. Humblias, M. Samson, M. Parmentier, J.P. Moore and C.R. Mackay. 1997. Interaction of chemokine receptor CCR5 with its ligands: multiple domains for HIV-1 gp120 binding and a single domain for chemokine binding. J. Exp. Med. 186:1373-1381;
	Y	Ylisastigui, L., J.J. Vizzanova, E. Drakopoulou, P. Paindavoine, C.F. Calvo, M. Parmentier, J.C. Gluckman, C. Vita and A. Benjoud. 1998. Synthetic full length and truncated RANTES inhibit HIV-1 infection of primary macrophages. AIDS 12:977-984.
	Z	Tilley, S. A., W.J. Honnen, S. Warrier, M.E. Racho, T.C. Chou, M. Girard, E. Muchmore, M. Hilgartner, D.D. Ho, M.S.C. Fung, and A. Pinter. 1991. Potent Neutralization of HIV-1 by Human and Chimpanzee Monoclonal Antibodies Directed Against Three Distinct Epitope Clusters of gp120. Sixieme Colloque Des Cent Gardes. 211-216;
	AA	Tilley, S.A., W.J. Honnen, M.E. Racho, T.C. Chou, and A. Pinter. 1992. Synergistic Neutralization of HIV-1 by Human Monoclonal Antibodies Against the V3 Loop and the CD4-Binding Site of gp120. AIDS Research and Human Retroviruses 80:4: 461-467;
	AB	Choe, H., M. Farzan, Y. Sun, N. Sullivan, B. Rollins, P.D. Ponath, L. Wu, C.R. Mackay, G. LaRosa, W. Newman, N. Gerard, C. Gerard, and J. Sodroski. The Beta-Chemokine Receptors CCR3 and CCR5 Facilitate Infection by Primary HIV-1 Isolates. Cell 85: 1135-1148;

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57906-B/JP[illegible]SHS/GJC	09/594,983
Applicants William C. Olson, et al.	
Filing Date June 15, 2000	Group

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U.S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation	
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

SHF	P	Kwong, P.D., R. Wyatt, J. Robinson, R.W. Sweet, J. Sodroski and W.A. Hendrickson. 1998. Structure of an HIV gp120 envelope glycoprotein in complex with the CD4 receptor and a neutralizing human antibody. Nature 393:648-659;
	Q	Laal, S., S. Burda, M.K. Gorny, S. Karwowska, A. Buchbinder and S. Zolla-Pazner. 1994. Synergistic neutralization of human immunodeficiency virus type 1 by combinations of human monoclonal antibodies. J. Virol. 68:4001-4008;
	R	Li, A., H. Katinger, M.R. Posner, L. Cavacini, S. Zolla-Pazner, M.K. Gorny, J. Sodroski, T.C. Chou, T.W. Baba and R.M. Ruprecht. 1998. Synergistic neutralization of simian-human immunodeficiency virus SHIV-vpu+by triple and quadruple combinations of human monoclonal antibodies and hig-titer antihuman immunodeficiency virus type 1 immunoglobulins. J. Virol. 72:3235-3240;
	S	Mack, M., B. Luckow, P.J. Nelson, J. Cihak, G. Simmons, P.R. Clapham, N. Signoret, M. Marsh, M. Stangassinger, F. Borlat, T.N.C. Wells, D. Schlondorff and A.E.I. Proudfoot. 1998. Aminooxypentane-RANTES induces CCR5 internalization but inhibits recycling: a novel inhibitory mechanisms of HIV infectivity. J. Ex. Med. 187:1215-1224;
	T	McKnight, A., D. Wilkinson, G. Simmons, S. Talbot, L. Picard, M. Ahuja, M. Marsh, J.A. Hoxie and P.R. Claphan. 1997. Inhibition of human immunodeficiency virus fusion by a monoclonal antibody to a co-receptor (CXCR3) is both cell type and virus strain dependent. J. Virol. 71:1692-1696;
	U	Strizki, J.M., J Davis-Turner, R.G. Collman, J. Hoxie and F. Gonzalez-Scarano. 1997. A monoclonal antibody (12G5) directed against CXCR4 inhibits infection with the dual-tropic human immunodeficiency virus type 1 isolate HIV-1 89.6 but not the T-tropic isolate HIV-1 HxB J. Virol. 71:5678-5683;
SHF	V	Trkola, A., T. Dragic, J. Arthos, J. Binley, W.C. Olson, G.P. Allaway, C. Cheng-Mayer, J. Robinson, P.J. Maddon and J.P. Moore. 1996. CD4-dependent, antibody sensitive interactions between HIV-1 and its co-receptor CCR-5. Nature 384:184-187;

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Form PTO-1449	U.S. Department of Commerce Patent and Trademark Office	Atty. Do[illegible] No. 57906-B[illegible]W/SHS/GJC	Serial No. 09/594,983
		Applicants William C. Olson, et al.	
	INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)	Filing Date June 15, 2000	Group

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FOREIGN PATENT DOCUMENTS

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

GH	I	Crump, M.P., J.H. Gong, P. Loetscher, K. Rajarathnam, A. Amara, R. Arenzana-Seisdedos, J.L. Virelizier, M. Baggiolini, B.D. Sykes and I. Clark-Lewis. 1997. Solution structure and basis for functional activity of stromal-cell derived factor-1; disassociation of CXCR4 activation from binding and inhibition of HIV-1. EMBO 16:6996-7007;
	J	Dalgleish, A.G., P.C.L. Beverly, P.R. Clapham, D.H. Crawford, M.F. Greaves and R.A. Weiss 1984. The CD4 (T4) antigen is an essential component of the receptor for the AIDS retrovirus Nature 312:763-766;
	K	Donzella, G.A., D. Schols, S.W. Lin, J.A. Este, K.A. Nagashima, P.J. Maddon, G.P. Allaway, T.P. Sakamar, G. Henson, E.D. Clercq and J.P. Moore. 1998 AMD3100, a small molecule inhibitor of HIV-1 entry via the CXCR4 co-receptor. Nat. Med. 4:72-77;
	L	Doranz, B.J., K. Grovit-Ferbas, M.P. Sharron, S.H. Mao, M.B. Goetz, E.S. Daar, R.W. Doms and W.A. O'Brien. 1997. A small molecule inhibitor directed against the chemokine receptor CXCR4 prevents its use as an HIV-1 co-receptor. J. Ex. Med. 186:1395-1400;
	M	Doranz, B.J., Z-H. Lu, J. Rucker, T.-Y Zhang, M. Sharron, Y.-H Cen, Z.-X. Wang, H.-H Guo, J.-G Du, M.A. Accavitti, R.W. Doms and S.C. Peiper. 1997. Two distinct CCR5 domains can mediate co-receptor usage by human immunodeficiency virus type 1. J. Virol. 71:6305-6314;
	N	Dragic, T., V. Litwin, G.P. Allaway, S.R. Martin, Y. Huanh, K.A. Nagashima, C. Cayanan, P.J. Maddon, R.A. Koup, J.P. Moore and W.A. Moore and W.A. Paxton. 1996. HIV-1 entry into CD4+ cells is mediated by the chemokine receptor CC-CKR-5. Nature 381:667-673;
GH	O	Hill, C.M., D. Kwon, M. Jones, C.B. Davis, S. Marmon, B.L. Daugherty, J.A. DeMartino, M.S. Springer, D. Unutmaz and D.R. Littman. 1998. The amino terminus of human CCR5 is required for its function as a receptor for diverse human and simian immunodeficiency virus envelope glycoproteins. Virology 248:257-371;

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Form PTO-1449	U.S. Department of Commerce Patent and Trademark Office	Atty. Dkt. No. 57906-B/JPW/SHS/GJC	Serial No. 09/594,983
		Applicants William C. Olson, et al.	
	INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)	Filing Date June 15, 2000	Group

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SHF	A	Allaway, G.P., K.L. Davis-Bruno, B.A. Beaudry, E.B. Garcia, E.L. Wong, A.M. Ryder, K.W. Hasel, M.C. Gaudin, R.A. Koup, J.S. McDougal and P.J. Maddon. 1995 Expression and characterization of CD4-IgG2, a novel heterotetramer that neutralizes primary HIV type 1 isolates. AIDS Res Hum Retroviruses 11:533-539;
	B	Allaway, G.P., A.M. Ryder, G.A. Beaudry and P.J. Maddon 1993. Synergistic inhibition of HIV-1 envelope-mediated cell fusion by CD4-based molecules in combination with antibodies to gp120 or gp41. AIDS Res. Hum. Retroviruses 9:581-587;
	C	Amara, A., S.L. Gall, O. Schwartz, J. Salamero, M. Montes, P. Loetscher, M. Baggiolini, J.L. Virelizier and F. Arenzana-Seisdedos. 1997. HIV coreceptor downregulation as antiviral principle: SDF-la-dependent internalization of the chemokine receptor CXCR4 contributes to inhibition of HIV replication. J. Exp. Med. 186:139-146;
	D	Berger, E.A. 1997. HIV entry and tropism: the chemokine receptor connection. AIDS 11 (suppl A): S3-S16;
	E	Bieniasz, P.D., R.A. Fridell, I. Aramori, S.S.G. Ferguson, M.C. Caron and B.R. Cullen. 1997. HIV-1 induced cell fusion is mediated by multiple regions within both the viral envelope and the CCR5 co-receptor. EMBO 16:2599-2609;
	F	Brelot, A., N. Heveker, O. Pleskoff, N. Sol and M. Alizon. 1997. Role of the first and third extracellular domains of CXCR4 in human immunodeficiency virus coreceptor activity. J. Virol. 71:4744-4751;
	G	Chan, D.C. and P.S. Kim. 1998. HIV entry and its inhibition. Cell 93:681-684;
SHF	H	Connor, R.I. K.E. Sheridan, D. Ceradini, S. Choe and N.R. Landau. 1997. Change in co-receptor use correlates with disease progression in HIV-1 infected individuals. J. Exp. Med. 185:621-628 ;

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	2/27/02

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INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)		Applicants William C. Olson, et al.	
		Filing Date June 15, 2000	Group 1646

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FOREIGN PATENT DOCUMENTS

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

GH	A	Fradd, B., M.E. McCarthy. 1989. AIDS Vaccines: An Investor's Guide by Shearman Lehman Hutton. Page 10 (Fig. 2) (Exhibit 1).
GH	B	De Rossi, A., M. Pasti, F. Mammano, M. Panozzo, M. Dettin, C. Di Bello and L. Chieco-Bianchi. 1991. Synthetic Peptides from the Principal Neutralizing Domain of Human Immunodeficiency Virus Type 1 (HIV-1) Enhance HIV-1 Infection through a CD4-Dependent Mechanism. Virology 184:187-196 (Exhibit 2).

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[signature]	2/27/02

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicants: William C. Olson
Serial No. : 09/594,983
Filed: June 15, 2000
Exhibit A

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities – 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/594,983	06/15/2000	William C. Olson	57906-B/JPW/SHS	8686

7590 03/13/2002

John P White
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER	
FOLEY, SHANON A	
ART UNIT	PAPER NUMBER
1648	10

DATE MAILED: 03/13/2002

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Applicant William C. Olson, et al. SMC

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Date September 13, 2002

Kindly acknowledge receipt of the accompanying

AMENDMENT IN RESPONSE TO MARCH 13, 2002 OFFICE ACTION AND PETITION FOR A THREE MONTH EXTENSION OF TIME in connection with William C. Olson, U.S. Serial No. 09/594,983, filed June 15, 2000 for SYNERGISTIC INHIBITION OF HIV-1 FUSION AND ATTACHMENT, COMPOSITIONS AND ANTIBODIES THERETO including Exhibit A (replacement Abstract), Exhibit B (replacement Figure 4), Exhibit C (amended claims), a check in the amount of $460.00, and an Express Mail Certificate dated September 13, 2002.

by placing your receiving date stamp hereon and returning to us.

Applicants : William C. Olson & Paul J. Maddon
U.S. Serial No. : 09/594,983
Filed : June 15, 2000

Exhibit 3